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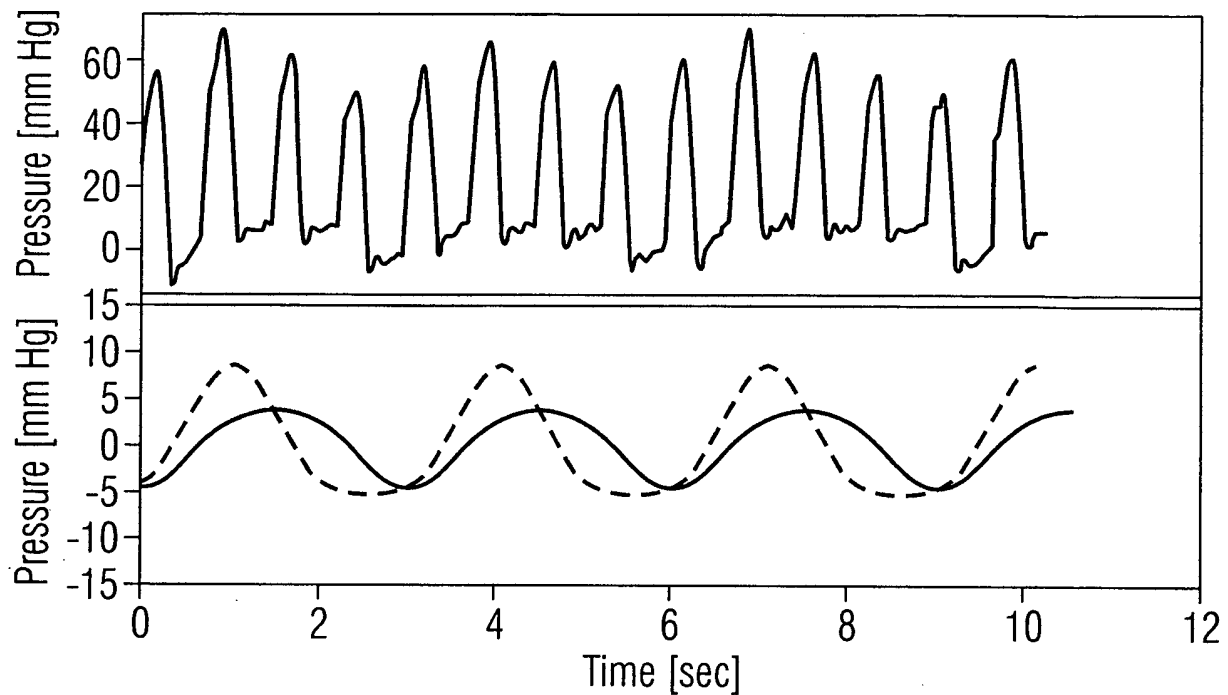
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(54) **Method and device for removing respiratory artefacts from measured blood pressure data**

(57) The invention relates to a method and a device for removing respiratory artefacts in invasive blood pressure measurements. The level of CO₂ in the expired air

is monitored during blood pressure measurement and used to approximate and remove the respiratory artefacts.

FIG 1



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Description

[0001] The invention relates to a method and device for removing artefacts caused by patient respiration in measured blood pressure data and in particular in blood pressure data acquired invasively in the heart and/or an artery of the patient.

[0002] In the diagnosis of cardiovascular diseases, cardiac catheterization can be a valuable tool for the cardiologist. During the procedure, the blood pressure can be invasively measured with catheters inserted into the patients heart or major arteries, and the blood pressure waveform is measured during several heart beats.

[0003] However, the blood pressure waveform is also affected by the work of the respiratory system, inducing a low-frequency variation in the waveform. The contraction of the diaphragm compresses and decompresses the lungs and thereby varies the intra-thoracic pressure. Since the pressure measured by the catheter is referred to atmospheric pressure, rather than the actual intra-thoracic pressure, there is a cyclic variation in the observed blood pressure at the respiratory frequency, caused by the patient's respiration.

[0004] A further effect of the intra-thoracic pressure variations caused by respiration is the increase of peripheral blood vessel resistance: Increased intra-thoracic pressure will also put pressure on the arteries, which will increase the right ventricular afterload. Afterload is the load the heart must eject blood against during systole. Further, increased pressure on the veins increases the filling of the left atrium, leading to an increased left ventricular output. The net effect of all this will be, that the diastolic pressure in the ventricles will be effected more or less directly by intra-thoracic pressure, while ventricular systolic pressure will be effected by an additional cyclic variation caused by changes in afterload, preload and intra-ventricular dependencies.

[0005] In addition, the heart-rate also varies with respiration, a phenomenon called respiratory sinus arrhythmia (RSA). During inspiration, there is an increase in heart-rate, in order to keep cardiac output constant in spite of the increased pressure resistance. Hence, RSA reduces variations in cardiac output caused by respiration, but in return causes large variations in the systolic pressure in the aorta. These variations often appear slightly phase-shifted from the effect of intra-thoracic pressure variations.

[0006] The three above described effects influence blood pressure measurements and lead to inaccurate results when calculating diagnostic parameters, such as systolic pressure (SP), beginning of diastolic pressure (BDP), and end diastolic pressure (EDP).

[0007] Previous attempts to compensate for these respiratory artefacts have merely used low-pass filters in order to filter out such components oscillating at about the respiratory frequency. Such methods are disclosed for example in the article by S.A. Hoeskel, J.R.C. Jansen, J.A. Blom und J.J. Screuder: "Correction for respiration artefacts in pulmonary blood vessel signals of ventilated patients", Journal of Clinical Monitoring, 12, pages 397 to 403, 1996.

[0008] It is an object of the invention to provide an improved method for removing respiratory artefacts in blood pressure measurements.

[0009] This object is achieved by the methods according to claims 1 and 13, as well as by the device according to claim 14. Preferred embodiments of the invention are defined in the respective dependent claims.

[0010] According to the method of claim 1, the level of CO₂ in the patient's expired air is acquired as a respiratory signal during the blood pressure measurement, and the respiratory signal is used to approximate and remove the artefacts caused by patient respiration. Hence, the invention makes use of the relationship between respiration and the level of CO₂ in the expired air. The CO₂ content may be measured by a straightforward method, for example using the equipment available from Oridion Systems Ltd. (see www.oridion.com). Here, the patient is connected to a cannula, e.g. nasally. Through the cannula, expired air is sampled by a pump which is placed in a bedside handheld monitor. The CO₂ level is analysed by a spectrometer positioned inside this monitor. Although there is a small time delay between respiration and the measured CO₂ content, this delay may easily be estimated and compensated for.

[0011] The respiratory signal may be used to calculate a model for the intra-thoracic pressure variations caused by respiration, and the influence on the diastolic and systolic blood pressure may be derived from the model. Hence, such pressure variations may be removed from the measured blood pressure waveform.

[0012] According to a first preferred embodiment, the level of CO₂ is measured over several breaths, and the respiratory frequency is extracted from the respiratory signal, preferably by identifying the end-tidal CO₂ level for each breath. The respiratory frequency is then used to derive a model for the respiratory artefacts, and the model is subtracted from the measured blood pressure data. Most preferred, the model is a linear Fourier combiner, e.g. a Fourier series having components at the respiratory frequency as well as higher order harmonics. The phase and amplitude of each component is adapted using an iterative algorithm, such as a recursive mean square algorithm, preferably having a forgetting factor, or a least mean square algorithm. Preferably, only first and second order harmonics, or first to third order harmonics are used. It has been shown that this method achieves even better results if only blood pressure data sampled during the diastolic period are chosen to adapt the phase and amplitude of each component. This is due to the above mentioned differences between variations in diastolic and systolic pressure. This method is particularly suitable for ventilated patients having a constant respiratory frequency.

[0013] According to a second preferred embodiment, a reference signal is generated from the measured respiratory

signal, the reference signal having a pre-determined function of the same length as the measured respiratory signal, a model for the respiratory artefacts is derived from the reference signal, and the model is subtracted from the measured blood pressure data. Preferably, the model is a finite impulse response model and, most preferred, it is adapted using an iterative algorithm, such as a recursive mean square algorithm or a least mean square algorithm. A finite impulse response filter is a system in which each output is a linear combination of a finite number of input data. This method is also called "adaptive noise canceller". It is based on the consideration that the respiratory artefacts are a disturbance which is correlated to a reference signal. The relationship between the reference signal and the disturbance may be established by an adaptive filter.

[0014] Preferably, the respiratory signal is analysed for generating the reference signal, wherein the start, stop and maximum data points for each breath may be calculated. From these values, a function having the same length as the measured respiratory signal is generated.

[0015] Preferably, the method also includes a step of compensating for respiratory sinus arrhythmia. In this step, preferably an ECG signal is recorded during the blood pressure measurement, and the instantaneous heart rate during the blood pressure measurement is calculated from the ECG signal, a relative heart rate is calculated as the difference between the instantaneous heart rate and the mean heart rate, the relative heart rate is used as input to an autoregressive model with exogenous input (ARX-model) for modelling the systolic blood pressure of each heart beat, which is adapted to the measured variations from the mean systolic blood pressure data, and the adapted autoregressive model is subtracted from the measured systolic blood pressure data. Preferably, the parameters of the autoregressive model are recursively adapted in order to derive the systolic pressure artefact caused by variation in heart rate. Further, the autoregressive model is preferably subtracted from the measured systolic blood pressure data in a way that does not alter the shape of the blood pressure waveform. This may be done for example by calculating a dampening constant between the end-diastolic pressure point and the begin-diastolic pressure point surrounding the systolic pressure that is being reduced.

[0016] According to a further aspect of the invention, a method for removing artefacts caused by patient respiration in measured blood pressure data is provided in which the measured blood pressure data are decomposed into several components by means of a wavelet transform, some of the components containing largely the respiration artefacts, wherein those components are optionally processed and then subtracted from the measured blood pressure data. A wavelet is a waveform of finite length having a mean value of 0. In contrast to the Fourier analysis, in which the signal is decomposed into sinus waves of infinite length, in wavelet analysis the signal is broken into local and often irregular and asymmetric wavelets. Hence, the wavelet transform is better suited for local functions.

[0017] The wavelet transform is defined as follows:

$$CWT_x^\psi(\tau, s) = \frac{1}{\sqrt{|s|}} \int x(t) \psi\left(\frac{t-\tau}{s}\right) dt \quad (1)$$

where ψ is the transforming function, the wavelet.

[0018] By applying a wavelet of about the same form as a blood pressure curve to the measured blood pressure data, the blood pressure data can be decomposed into several components. The blood pressure curve is essentially contained in one or two components, while the respiratory artefacts will fall under decomposition levels of higher scale (lower frequency). Hence, these components may be subtracted from the measured data in order to remove respiration artefacts.

[0019] The invention is further directed to a device for acquiring and correcting blood pressure data, having a catheter insertable into the heart or an artery for measuring blood pressure, the device further containing a sensor for measuring the level of CO₂ in the patient's expired air as a respiratory signal, and a data processing module for removing artefacts in the measured blood pressure data, wherein the data processing module is adapted to use the respiratory signal to approximate and to remove the artefacts caused by patient respiration. Preferably, the device is adapted to carry out the above described method.

[0020] Preferred embodiments of the invention shall now be described with reference to the accompanying drawings, in which:

Fig. 1 shows a graph of measured blood pressure signal versus time, as well as estimated artefacts in diastolic and systolic pressure;

Fig. 2 shows a graph of the measured CO₂ level versus time;

Fig. 3 shows a flow chart of a first embodiment of the method according to the invention;

Fig. 4 shows a flow chart of a second embodiment of the method according to the invention;

Fig. 5 shows a graph of measured CO₂ level and a reference signal;

5 Fig. 6 shows the waveform of a heart beat to be compensated.

[0021] To visualize the respiratory artefacts in measured blood pressure, fig. 1 depicts the measured blood pressure in the right ventricle, as well as the estimated respiratory artefacts. The solid curve shows artefacts considered as variations in diastolic pressure, and the dashed curve artefacts considered as variations in systolic pressure.

10 **[0022]** Fig. 2 shows the respiratory signal which is a signal of the amount of CO₂ in expired air.

[0023] With regard to fig. 3, the first embodiment of the invention shall now be explained in detail. The measured blood pressure signal $y(t)$ can be described as the correct blood pressure $s(t)$ and a disturbance $v(t)$ caused by respiration:

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$$y(t) = s(t) + v(t) \quad (2)$$

[0024] The disturbance $v(t)$ may be described as a series of sinusoids, called a dynamic Fourier series model. The coefficients of this series are dynamically adapted. This concept is called an adaptive Fourier linear combiner. A flow chart of an adapted Fourier linear combiner is shown in fig. 3. The fundamental frequency of this model is the respiratory frequency ω_0 , which can be extracted from the respiratory signal and used to model the respiratory disturbance in the blood pressure as

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$$\hat{v}(w, t) = \omega_0(t) + \sum_{k=1}^M [\omega_{2k-1}(t) \sin(\omega_0 t k) + \omega_{2k}(t) \cos(\omega_0 t k)] \quad (2)$$

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$$w(t) = [\omega_0(t), \omega_1(t), \dots, \omega_{2M}(t)]^T \quad (3)$$

35 **[0025]** An approximation to the correct blood pressure $s(t)$ is then:

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$$\hat{s}(t) = y(t) - \hat{v}(w, t) \quad (4)$$

[0026] The phase and the amplitude of a respiratory signal $v(w, t)$ is estimated when adapting equation (4) by adjusting the weights w using an adaptive algorithm. Different adaptive algorithms can be used such as the recursive mean square algorithm or the least mean square algorithm.

[0027] This system acts as a kind of adaptive band stop filter for the respiratory frequency ω_0 and its M harmonics.

45 **[0028]** If the number of coefficients is set too high, components from the correct blood pressure waveform may be described by the Fourier series and therefore falsely removed. To ensure that this does not happen, the length of the series is preferably set so that the highest frequency that can be described by the series is lower than the heart rate. If the heart rate is ω_1 , this gives a maximum limit for

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$$M \leq \frac{\omega_1}{\omega_0} \quad (5)$$

55 rounded downwards to the closest integer value. In the experiments, $M = 2$ was enough to give a good result. However, third, fourth and higher order harmonics may also be included.

[0029] Preferably, only such blood pressure data measured during the diastolic phase are used. This leads to a faster convergence of the algorithm.

[0030] With reference to fig. 4, a second embodiment of the method according to the invention shall now be described. In this so-called "adaptive noise canceller", a reference signal $u(t)$ for the disturbance $v(t)$ is calculated which is highly correlated with the disturbance. The output of the adaptive filter $\hat{y}(t)$ will be subtracted from the measured signal $y(t)$ to form an error signal $\varepsilon(t)$ which is used to update the filter. This would be an estimate to $s(t)$, the correct blood pressure.

[0031] However, this method cannot be used directly in this case, because there is no correct reference signal for the disturbance. The measured respiratory signal is a measurement of the level of CO_2 , not the intra-thoracic pressure, and must first be processed before it can be used as a reference. This difference is demonstrated by fig. 5, which shows the measured respiratory signal on the left and the corresponding actual artefact, approximated from the blood pressure signal, on the right.

[0032] Therefore, from the acquired respiratory signal, a reference signal is generated. To generate this new signal, the measured respiratory signal is analysed and the start, stop, and a maximum point for each breath is calculated. From the calculated values, a function having the same length as the original is generated, preferably by adjusting a sinus-curve.

[0033] Preferably, the reference signal has the following formula:

$$p(t) = \begin{cases} A_{\text{insp}} \sin(t), & 0 \leq t < \pi/2 \\ A_{\text{insp}} \left(\sin(t) - (\sin(t) - 1) \frac{1+A_{\text{exp}}}{2} \right), & \pi/2 \leq t < 3\pi/2 \\ -A_{\text{exp}} \sin(t), & 3\pi/2 \leq t < 2\pi \end{cases} \quad (6)$$

where A_{exp} is the expected change in pressure during an expiration compared to the inspiration A_{insp} . If the patient is free breathing, the value of A_{insp} is assumed to be about minus A_{exp} , meaning the change during expiration is the opposite of inspiration. For a mechanically ventilated patient, A_{exp} can be assumed to be around $0.1 A_{\text{insp}}$, indicating a constant positive pressure.

[0034] The change in amplitude between breath is adjusted by the variable A_{insp} which is set to the maximum point R_{max} .

[0035] When a reference signal has been created, the actual compensation can begin. The reference signal is thereby used to model an approximation to the respiratory artefacts $y(t)$. This may be done by describing $y(t)$ as a finite impulse response model defined as

$$\hat{y}(t) = w_1(t)u(t-1) + \dots + w_m(t)u(t-m) + e(t) \quad (6)$$

[0036] The filter weights $w_1 \dots w_m$ can then be updated according to a normalized mean square or a recursive mean square algorithm.

[0037] If the low-frequency variations in the diastolic pressure appear as a phase-shifted version in systolic pressure (see fig. 1) a normal filter approach will not give a correct result. To counter this problem, only the end-diastolic pressure is used for updating the adaptive algorithm. This ensures that the correct respiratory artefact is reduced.

[0038] In order to compensate for artefacts caused by RSA a further method step is suggested. After removing the artefacts caused by intra-thoracic pressure variations by one of the above described methods, the remaining artefacts may be removed as follows:

[0039] First, a measure for RSA must be found. This is done by using an ECG-signal to calculate the instantaneous heart rate over the measurement period. If an ECG is taken over several heart beats, a mean heart rate may be calculated as well. This is used to calculate the relative heart rate r , defined as the difference of the actual heart rate to the mean rate over a given time window.

[0040] The compensation method then consists in calculating a compensation according to the change in instantaneous heart rate. This is done by letting the remaining systolic pressure variations be modelled as an ARX-model (autoregressive model with exogenous input) with input $r(n)$, corresponding to the change in heart rate. If the systolic pressure for the current heart beat n is denoted $p_{\text{sp}}(n)$, the variation from the mean systolic pressure over 1 heart beats may be denoted as $p_{\text{SPVar}}(n)$.

[0041] The ARX-model can then be written as

$$\hat{p}_{SPVar}(n) + a_1(n)\hat{p}_{SPVar}(n-1) + \dots + a_N(n)\hat{p}_{SPVar}(n-N) = b_1(n)r(n-1) + \dots + b_M(n)r(n-M) + e(n) \quad (7)$$

[0042] An adaptive algorithm will update the parameters recursively in a similar way as the above mentioned FIR-model to minimize the model error between the actual and the calculated $p_{SPVar}(n)$. The forgetting factor may be set to about 0.95, i.e. about 20 beats are remembered, which gives a fast convergence. The output $p_{SPVar}(n)$ is the systolic pressure originating from heart rate variations. That is the amount that should be removed from the measured systolic pressure $p_{sp}(n)$.

[0043] This should preferably be done in a way that the shape of the pressure waveform will remain the same. To do this, a dampening constant is calculated between the end-diastolic pressure point $p_{EDP}(n)$ and the begin-diastolic pressure point $p_{BDP}(n+1)$ surrounding the systolic pressure $p_{sp}(n)$ that is being reduced. This is illustrated in fig. 6. A dampening constant $d(n)$ is then set so the systolic pressure $p_{sp}(n)$ is reduced by $p_{SPVar}(n)$:

$$d(n) = \frac{p_{sp}(n) - b(n) - \hat{p}_{SPVar}(n)}{p_{sp}(n) - b(n)} \quad (8)$$

[0044] Every pressure sample $p(t)$ between τ_1 and τ_2 is altered in a way that reduces the systolic pressure in a smooth way, such that the shape of the waveform will be preserved.

Claims

1. A method for removing artefacts caused by patient respiration in measured blood pressure data, in particular in blood pressure data acquired invasively in the heart and/or an artery of the patient,

characterized in that

- the level of CO_2 in the patient's expired air is acquired as a respiratory signal during the blood pressure measurement, and
- the respiratory signal is used to approximate and remove the artefacts caused by patient respiration.

2. The method of claim 1,

characterized in that

- the level of CO_2 is measured over several breaths, and the respiratory frequency is extracted from the respiratory signal, in particular by identifying the end-tidal CO_2 level for each breath,
- the respiratory frequency is used to derive a model for the respiratory artefacts, and
- the model is subtracted from the measured blood pressure data.

3. The method of claim 2,

characterized in that

- the model is a Fourier Linear Combiner having components at the respiratory frequency and higher order harmonics, wherein the phase and amplitude of each component is adapted using an iterative algorithm, such as a Recursive Mean Square Algorithm.

4. The method of claim 3,

characterized in that

the highest frequency in the Fourier Linear Combiner is the second, third or fourth order harmonic.

5. The method of claim 3 or 4,

characterized in that

only blood pressure data sampled during the diastolic period are chosen to adapt the phase and amplitude of each component.

6. The method of claim 1
characterized in that

- a reference signal is generated from the measured respiratory signal, the reference signal having a predetermined function of the same length as the measured respiratory signal,
- a model for the respiratory artefacts is derived from the reference signal, and
- the model is subtracted from the measured blood pressure data.

7. The method of claim 6,
characterized in that

the model is a finite impulse response model and, in particular, is adapted using an iterative algorithm, such as a Recursive Mean Square Algorithm.

8. The method of claim 7,
characterized in that

only blood pressure data sampled during the diastolic period are chosen to adapt the finite impulse response model.

9. The method of one of claims 6 to 8,
characterized in that

the respiratory signal is analysed for generating the reference signal, wherein the start, stop and maximum data points for each breath are calculated.

10. The method of one of the preceding claims,
characterized in that it further comprises a step of compensating for Respiratory Sinus Arrhythmia.

11. The method of claim 10,
characterized in that

- an ECG signal is recorded during the blood pressure measurement, and the instantaneous heart rate during the blood pressure measurement is calculated from the ECG signal,
- a relative heart rate is calculated as the difference between the instantaneous heart rate and the mean heart rate,
- the relative heart rate is used as input to an autoregressive model with exogenous input for modelling the systolic blood pressure of each heart beat, which is adapted to the variations in the measured systolic blood pressure data, and
- the adapted autoregressive model is subtracted from the measured systolic blood pressure data.

12. The method of claim 11,
characterized in that

- the autoregressive model is subtracted from the measured systolic blood pressure data in a way that does not alter the shape of the blood pressure waveform.

13. A method for removing artefacts caused by patient respiration in measured blood pressure data, in particular in blood pressure data acquired invasively in the heart and/or an artery of the patient,
characterized in that

- the measured blood pressure data are decomposed into several components by means of a wavelet transform, some of the components containing largely the respiratory artefacts, and
- in that** those components are optionally processed and subtracted from the measured blood pressure data.

14. A device for acquiring and correcting blood pressure data, having a catheter insertable into the heart or an artery for measuring blood pressure,
characterized in that

- the device further contains a sensor for measuring the level of CO₂ in the patient's expired air as a respiratory signal, and
- a data processing module for removing artefacts in the measured blood pressure data, wherein the data processing module is adapted to use the respiratory signal to approximate and remove the artefacts caused

by patient respiration.

15. The device of claim 14,
characterized in that

5 it is adapted to carry out the method of one of claims 1 to 13.

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FIG 1

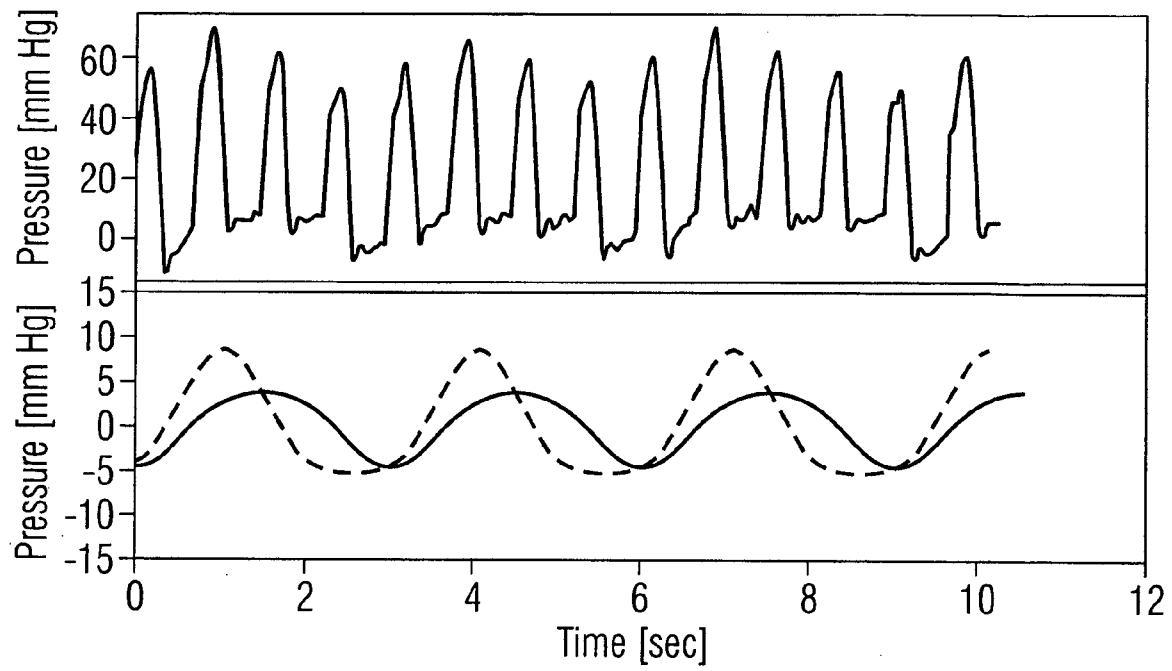


FIG 2

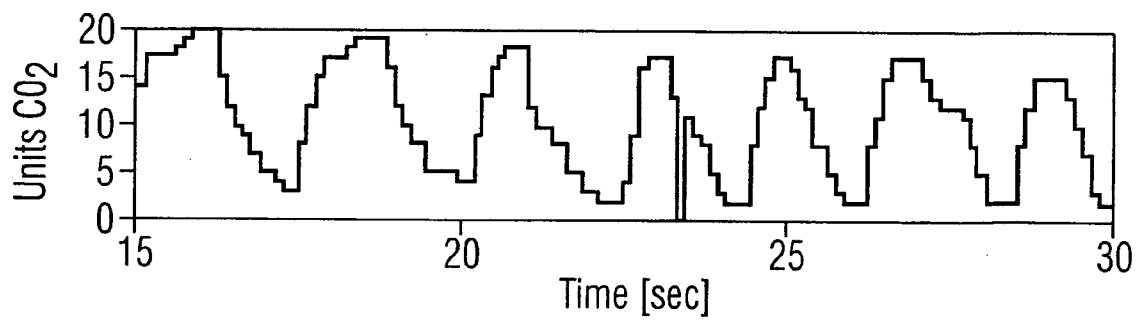


FIG 3

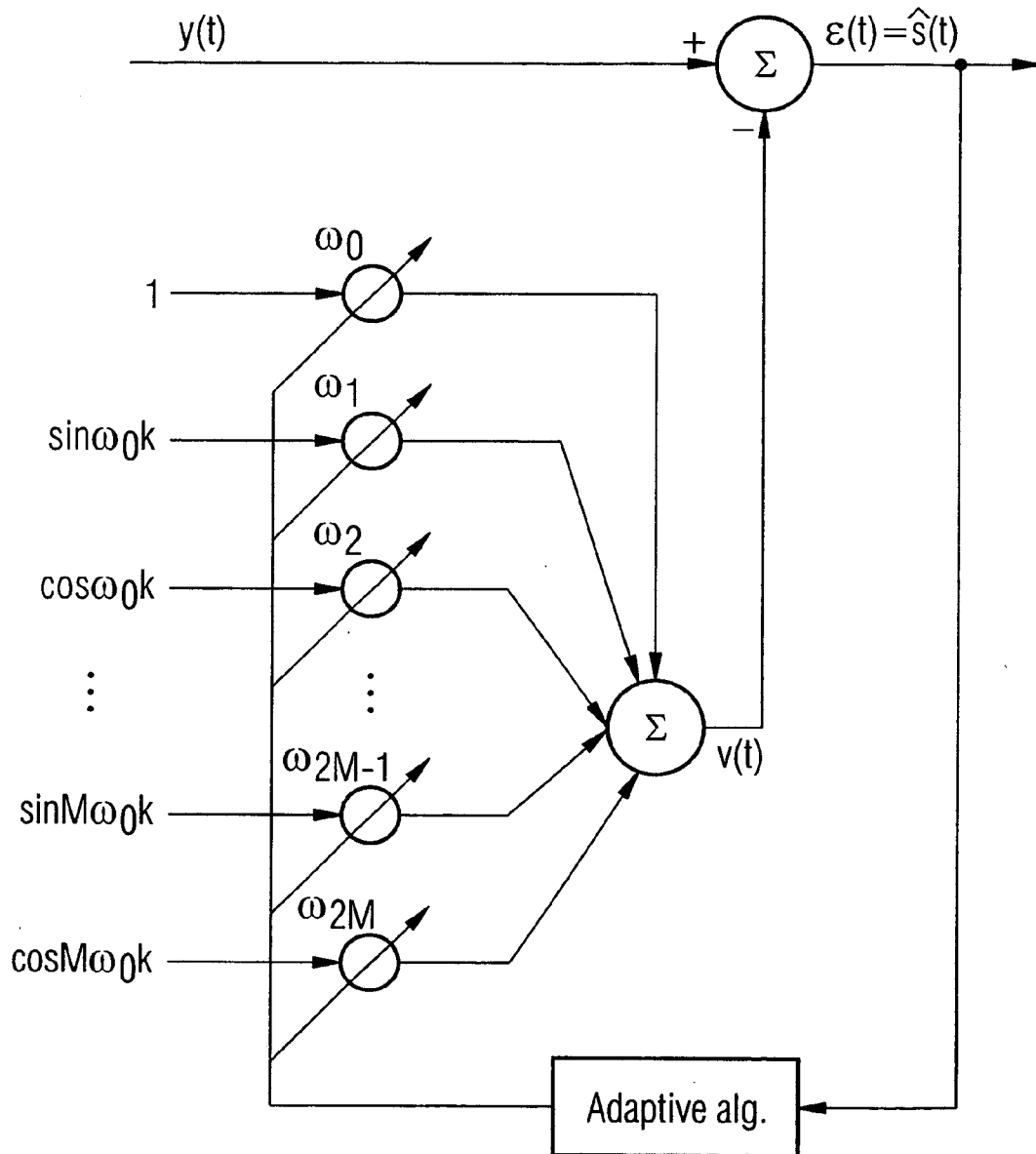


FIG 4

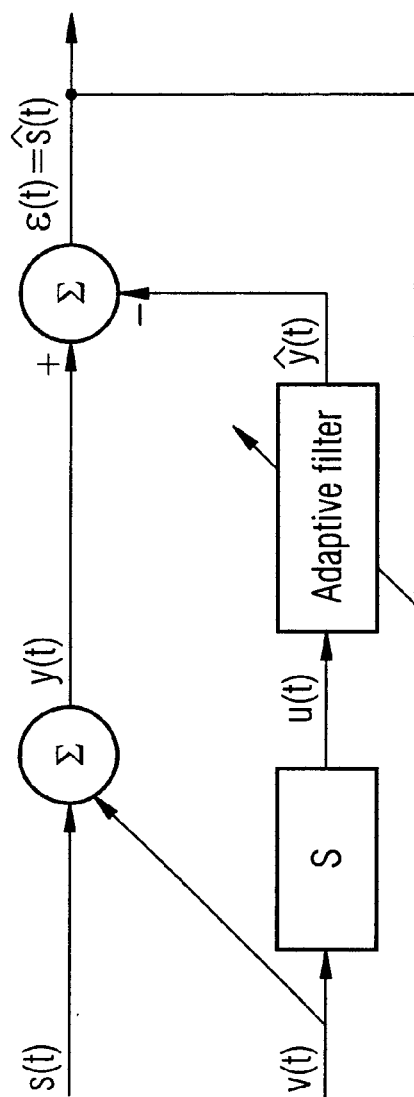


FIG 5

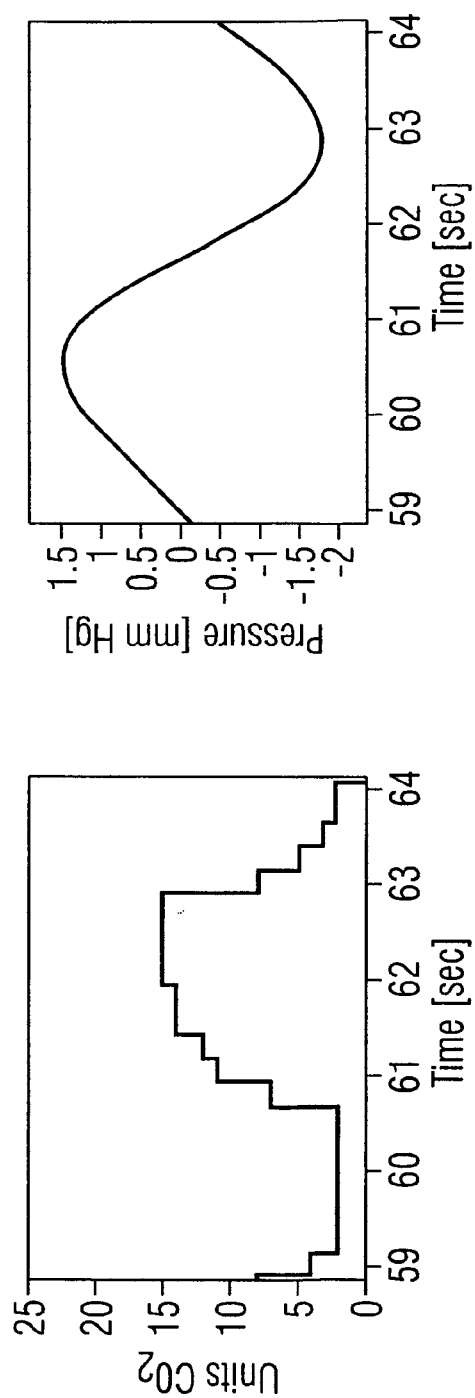
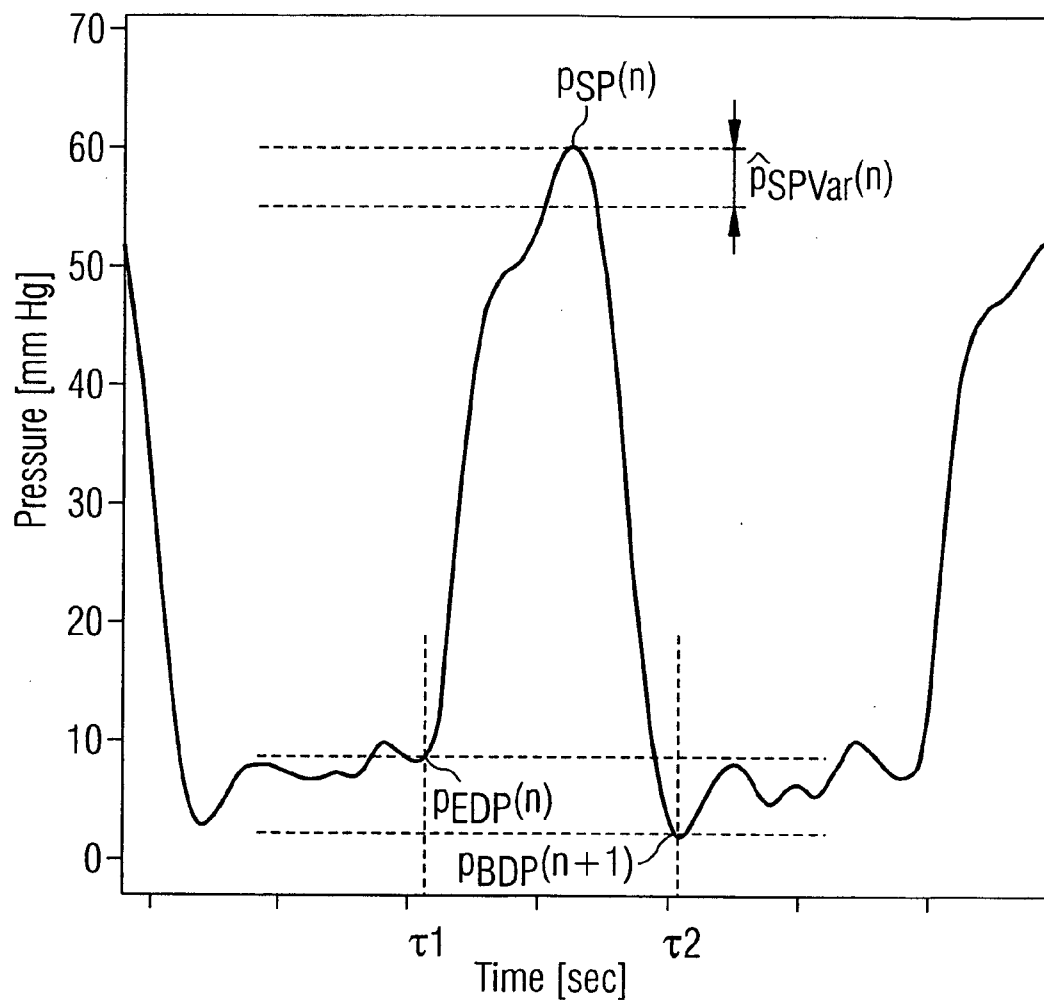


FIG 6





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Application Number

which under Rule 45 of the European Patent Convention EP 05 02 1339 shall be considered, for the purposes of subsequent proceedings, as the European search report

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			TECHNICAL FIELDS SEARCHED (IPC)
			A61B
INCOMPLETE SEARCH The Search Division considers that the present application, or one or more of its claims, does/do not comply with the EPC to such an extent that a meaningful search into the state of the art cannot be carried out, or can only be carried out partially, for these claims. Claims searched completely : Claims searched incompletely : Claims not searched : Reason for the limitation of the search: see sheet C			
Place of search		Date of completion of the search	Examiner
The Hague		6 March 2006	Hunt, B
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Claim(s) searched completely:
14, 15

Claim(s) not searched:
1-13

Reason for the limitation of the search (non-patentable invention(s)):

Article 52 (4) EPC - Method for treatment of the human or animal body by surgery where independent claims 1 and 13 both involve blood pressure data acquired invasively, i.e. a surgical step is required, and this invasive method is the only method supported by the description.

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 05 02 1339

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06-03-2006

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